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In the Supreme Court of the United States

OCTOBER TERM, 1963

No. 833

SIDNEY STEINSCHREIBER, DOING BUSINESS AS SIDCAPS LABORATORIES, JOHN P. CALISE, WESTCHESTER BLOOD SERVICE, INC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (II R. 310–311; Pet. App. A1–2) [1] is reported at 326 F. 2d 759. The opinions of the district court (I R. 5–8; 9–32; 33) are reported at 218 F. Supp. 426 and 219 F. Supp. 373.

JURISDICTION

The judgment of the court of appeals was entered on January 17, 1964 (II R. 312). The petition for a writ of certiorari was filed on February 14, 1964. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

[1] The record on file with the Clerk of this Court consists of the appendices to the briefs of the parties filed in the court of appeals. The appendix to petitioners' brief is designated "I R." and the appendix to the government's brief is denoted "II R."

QUESTIONS PRESENTED

1. Whether normal human blood plasma is a product "analogous to therapeutic serum" within the meaning of Section 351 of the Public Health Service Act.

2. Whether Section 351 of the Public Health Service Act is sufficiently clear and definite to sustain a criminal prosecution for its violation.

3. Whether the district court, sitting without a jury, properly allowed into evidence expert testimony that normal human blood plasma is a product "analogous to therapeutic serum."

STATUTE AND REGULATIONS INVOLVED

Section 351 of the Public Health Service Act, 58 Stat. 682, 702, as amended, 42 U.S.C. 262, provides in pertinent part:

> "(a) No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, or other product has been propagated or manufactured and prepared at an establishment hold-

ing an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; and (2) each package of such virus, serum, toxin, antitoxin, or other product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results. The suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, or other product aforesaid which has been sold and delivered by the licensee prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, or other product aforesaid has been notified by the Secretary not to sell, barter, or exchange the same.

(b) No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, or other product aforesaid so as to falsify such label or mark.

* * * * *

(f) Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a

fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

42 C.F.R. 73.1 (1963 ed.) provides in pertinent part:

* * * * *

(i)(2) A therapeutic serum is the product obtained from the blood of an animal by removing the clot or clot components and the blood cells, and not intended for ingestion.

* * * * *

(i)(5) A product is analogous:

* * * * *

(ii) To a therapeutic serum, if composed of whole blood or plasma or containing some organic constituent or product other than a hormone or an amino acid, derived from whole blood, plasma, or serum, and not intended for ingestion.

* * * * *

STATEMENT

After a trial by the court, sitting without a jury, petitioners were convicted in the United States District Court for the Southern District of New York of violation of Section 351 of the Public Health Service Act. This statute proscribes the transportation for sale, barter or exchange of enumerated biological products including "therapeutic serum * * * or analogous product," which have been produced at an unlicensed establishment and prohibits the false labeling of the containers of any such products. In this case petitioners were charged with having illegally transported and mislabeled dried normal human blood plasma. Petitioner Steinschreiber was sentenced to three months' imprisonment on each of counts 1–8

and 10–15, the sentences to run concurrently, with execution of the sentence suspended on count 1 and probation of two years to commence after completion of the prison sentence. Petitioner Calise was sentenced to six months' imprisonment on count 1, with four months of the sentence suspended, to be followed by two years of probation. Petitioner Westchester Blood Service, Inc., was fined $500. The court of appeals affirmed *per curiam* on the opinion of the district court, reported at 219 F. Supp. 373.[2]

Petitioners had moved to dismiss an earlier indictment on the ground that normal human blood plasma was not a product analogous to a therapeutic serum as charged in the indictment, and that if the statute was construed to encompass normal human blood plasma it would be void for vagueness. The district court denied the pretrial motion, noting that whether "as a scientific fact normal human plasma and therapeutic serum are analogous products * * * is a matter to be resolved on the trial by the expert and special knowledge of witnesses who may be called by the Government or by the defendants" (248 F. Supp. at 427). A similar motion to dismiss the present indictment (which superseded the earlier one) was also overruled before trial.

During the trial, over defense objection (*e.g.*, I R. 34–38, 48–49, 57–59), the government presented the testimony of three expert witnesses who stated that dried normal human blood plasma was a "product analogous to therapeutic serum" (*e.g.*, I R. 40–45, 67;

[2] The facts, which are not in dispute, are detailed in the opinion of the trial court (219 F. Supp. 373, 375–378).

II R. 67–70; 83–84). As one expert put it, plasma "is so analogous, is so close to being serum, that it practically is serum" (II R. 70). In its opinion at the conclusion of the trial, the district court made the following findings of fact: "that human plasma and human serum are identical * * * and that the only dissimilarity is that serum is plasma from which the fibrinogen, or clotting component, has been removed"; and that "[f]or many therapeutic uses plasma and serum are interchangeable * * * and the same constituent elements which are significant in such therapeutic uses are present in both," 219 F. Supp. at 382. The trial court further found that the legislative history of the statute and the regulations promulgated thereunder supported the view that Congress intended the statute to cover the manufacture and sale of normal human blood plasma, 219 F. Supp. at 382–383.

ARGUMENT

1. Petitioners' contention that Congress did not intend the terms "therapeutic serum * * * or analogous product" to embrace normal human blood plasma is refuted by the language of the statute, its legislative history and administrative interpretation.

In both the ordinary and scientific sense, the language of Section 351 embraces human blood plasma. In Webster's *Third New International Dictionary* (Unabridged, 1961 ed.) p. 1732, plasma is defined as "the fluid part of blood, * * * differing from serum essentially in containing the antecedent substance of

fibrin in addition to the constituents of serum".[3] The expert testimony at trial unanimously confirmed the scientific truth of this common definition (I R. 40–45; II R. 67–74; 83–85).

The legislative history of the statute and its administrative interpretation also support the view that the statute covers blood plasma. The Act was originally adopted in 1902, 32 Stat. 728, to insure the purity of those animal substances used in the "prevention and cure of disease" as were "introduced into the circulation directly" rather than by ingestion, since it was believed the former required more meticulous supervision of their manufacture and sale. See S. Rep. No. 1980, 57th Cong., 1st Sess. (1902), p. 2; H. Rep. No. 2713, 57th Cong., 1st Sess. (1902), p. 2. Normal human blood plasma fits in this category because it is administered directly into the bloodstream rather than into the digestive tract. The statute's failure to refer explicitly to blood plasma does not mean that Congress intended to exclude this product from the Act's coverage. Congress dealt with general classes—"virus, therapeutic serum, toxin, antitoxin,"—and concluded with the broad terms "or analogous product" so as to have the statute apply to subsequent scientific discoveries of new biological products for the "prevention, treatment or cure of diseases or injuries of man * * *." Hence the fact that human blood plasma was not in general use when the legislation was enacted in 1902

[3] As the trial judge pointed out, this dissimilarity is insignificant since a substantial portion of fibrinogen is precipitated out before plasma is used. 219 F. Supp. at 382.

does not affect the statute's current application to plasma.

The fact that Congress added arsphenamine—a product used in the treatment of syphilis—to the categories of covered products in 1944 and did not then enumerate human blood plasma in the statute (see Pet. 7a) is of no significance. At that time Congress was well aware of the fact that the Act was administratively construed to apply to normal human blood plasma. The regulations defined therapeutic serum as a "product obtained from * * * blood" ~~and further provided that a product was analogous "if composed of whole blood or plasma" [emphasis added]~~ (see 42 C.F.R. 73.1(i)(2), and 42 C.F.R. 73.1(i)(5)(ii), p. 4, *supra*).[1] Moreover, an official of the National Institutes of Health explicitly testified before Congressional committees before the passage of the 1944 Act that the NIH was licensing the preparation and distribution of human blood plasma.[1] Apart from the familiar principle that the views of an expert agency as to the meaning and scope of a statute it enforces are entitled to considerable weight (*e.g.*, *F.H.A.* v. *The Darlington, Inc.*, 358 U.S. 84, 90; *County of Marin* v. *United States*, 356 U.S. 412, 420; *Boutell* v. *Walling*, 327 U.S. 463, 471), the re-enactment of the statute in 1944 without material change reflects a Congressional affirmation of the settled administrative

[1] See Hearings Before the House Subcommittee of the Committee on Appropriations on The First Deficiency Appropriations Bill for 1943, 78th Cong., 1st Sess. (1943), p. 8; Hearings Before the House Subcommittee of the Committee on Appropriations on The Department of Labor—Federal Security Appropriation Bill for 1944, Part 2, 78th Cong., 1st Sess. (1943), p. 358.

interpretation. See *F.H.A.* v. *The Darlington, Inc., supra; National Labor Rel. Board* v. *Gullett Gin Co.*, 340 U.S. 361, 365–366.

There is no substance to petitioners' assertion (Pet. 7, 12–13) that, since the regulations define therapeutic serum as "the product obtained from the blood of an animal" human blood plasma cannot be an "analogous product." In the commonly understood biological sense, the term "animal" includes human beings. Likewise baseless is the argument that since regulations exist which deal with human whole blood and human packed red blood cells (42 C.F.R. 73.300 *et seq.*) the absence of any reference to human blood plasma reflects an administrative judgment that such plasma was not to be regulated by the statute. The inclusion of blood plasma in the definition of a product analogous to a therapeutic serum (42 C.F.R. 73.1(i)(5)(ii)) rendered unnecessary any further regulations relating specifically to plasma.

2. Petitioners accept the fact-findings of the trial court (Pet. 6), and thereby admit that they knew from the inception of their scheme that a license had to be obtained for the preparation and sale of blood plasma. 219 F. Supp. at 375. Notwithstanding this finding, they contend that neither the statute nor the regulations gave them sufficient notice that human blood plasma was covered by Section 351. As this Court recently observed in *United States* v. *National Dairy Corp.*, 372 U.S. 29, 33, "In determining the sufficiency of the notice a statute must of necessity be examined in the light of the conduct with which a defendant is charged." The facts in the present case

clearly support the district court's conclusion (219 F. Supp. at 382) that "* * * there is persuasive evidence that the statutory references to biological terms which may not have been initially clear to this court were in fact clear to these defendants at the time of the offenses charged in this indictment." Under the circumstances the petitioners' asserted constitutional claims are without merit.

3. There is also no merit to petitioners' contention that it was error to admit expert testimony that normal human blood plasma is analogous to therapeutic serum. Those dealing in medical products must be held to the technical definitions of statutory terms; otherwise the statute would be totally unenforceable. Moreover, the trial judge relied on uncontroverted scientific evidence and on the legislative history of the statute, as well as on the testimony of the experts. 219 F. Supp. at 382–383. Hence the decision as to the applicability of the statute was based upon his independent judgment, and not on the testimony of the experts only.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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